

TDMS No. 20201 - 03

Test Type: 26-WEEK

Route: SKIN APPLICATION

Species/Strain: MICE/TG.AC HEMI

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC
LESIONS ABRIDGED) (a)**

TEF TRANSGENICS (PECDF)

CAS Number: 57117-31-4

Date Report Reqsted: 06/14/2006

Time Report Reqsted: 15:27:08

First Dose M/F: NA / 04/21/03

Lab: BAT

C Number: C20201C

Lock Date: 07/24/2004

Cage Range: ALL

Date Range: ALL

Reasons For Removal: ALL

Removal Date Range: ALL

Treatment Groups: Include ALL

Test Type: 26-WEEK

Time Report Requested: 15:27:08

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Lab: BAT

TGAC (FVB/N) HEMIZYGOUS MICE FEMALE	0 NG/KG	72 NG/KG	242 NG/KG	720 NG/KG	1520 NG/KG
Disposition Summary					
Animals Initially in Study	20	20	20	20	20
Early Deaths					
Moribund Sacrifice	1	4	3	7	6
Natural Death	2	3	1		1
Survivors					
Moribund Sacrifice					1
Terminal Sacrifice	17	13	16	13	12
Animals Examined Microscopically	20	20	20	20	20
ALIMENTARY SYSTEM					
Liver	(20)	(20)	(20)	(20)	(20)
Mesentery	(1)	(1)	(0)	(0)	(0)
Pancreas	(0)	(1)	(0)	(0)	(0)
Salivary Glands	(1)	(0)	(0)	(0)	(0)
Squamous Cell Carcinoma	1 (100%)				
Stomach, Forestomach	(6)	(2)	(2)	(5)	(8)
Squamous Cell Papilloma	4 (67%)	1 (50%)	1 (50%)	5 (100%)	4 (50%)
Squamous Cell Papilloma, Multiple	1 (17%)	1 (50%)	1 (50%)		4 (50%)
Stomach, Glandular	(1)	(0)	(0)	(0)	(0)
Tooth	(6)	(6)	(3)	(1)	(2)
Odontogenic Tumor	5 (83%)	5 (83%)	2 (67%)		2 (100%)
Odontogenic Tumor, Multiple	1 (17%)	1 (17%)			
CARDIOVASCULAR SYSTEM					
Heart	(0)	(0)	(0)	(0)	(1)
ENDOCRINE SYSTEM					
Pituitary Gland	(0)	(0)	(1)	(1)	(0)
GENERAL BODY SYSTEM					
None					

a - Number of animals examined microscopically at site and number of animals with lesion

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GENITAL SYSTEM					
None					
HEMATOPOIETIC SYSTEM					
Lymph Node	(0)	(0)	(0)	(8)	(4)
Spindle Cell Carcinoma, Metastatic, Skin, Site Of Application				1 (13%)	1 (25%)
Squamous Cell Carcinoma, Metastatic, Lymph Node				1 (13%)	
Squamous Cell Carcinoma, Metastatic, Skin				3 (38%)	3 (75%)
Mediastinal, Squamous Cell Carcinoma, Metastatic, Skin				1 (13%)	
Thoracic, Squamous Cell Carcinoma, Metastatic, Skin					1 (25%)
Lymph Node, Mandibular	(0)	(1)	(0)	(3)	(3)
Squamous Cell Carcinoma, Metastatic, Skin				1 (33%)	1 (33%)
Lymph Node, Mesenteric	(1)	(1)	(0)	(2)	(1)
Spleen	(20)	(20)	(20)	(20)	(20)
Thymus	(20)	(19)	(19)	(19)	(18)
INTEGUMENTARY SYSTEM					
Skin	(4)	(4)	(8)	(7)	(13)
Squamous Cell Papilloma		4 (100%)	3 (38%)	1 (14%)	7 (54%)
Squamous Cell Papilloma, Multiple				3 (43%)	5 (38%)
Skin, Control Dermis	(20)	(20)	(20)	(20)	(20)
Skin, Control Epidermis	(20)	(20)	(20)	(20)	(20)
Skin, Site Of Application	(20)	(20)	(20)	(20)	(20)
Keratoacanthoma		1 (5%)		1 (5%)	
Spindle Cell Carcinoma			1 (5%)	1 (5%)	3 (15%)
Spindle Cell Carcinoma, Multiple					1 (5%)
Squamous Cell Carcinoma		1 (5%)	2 (10%)	5 (25%)	5 (25%)
Squamous Cell Carcinoma, Multiple				4 (20%)	7 (35%)
Squamous Cell Papilloma	1 (5%)	5 (25%)	1 (5%)	1 (5%)	
Squamous Cell Papilloma, Multiple		10 (50%)	16 (80%)	19 (95%)	20 (100%)
Skin, Soa No Mass	(20)	(20)	(17)	(13)	(12)

a - Number of animals examined microscopically at site and number of animals with lesion

TGAC (FVB/N) HEMIZYGOUS MICE FEMALE	0 NG/KG	72 NG/KG	242 NG/KG	720 NG/KG	1520 NG/KG
MUSCULOSKELETAL SYSTEM					
None					
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
Lung	(20)	(20)	(20)	(20)	(20)
Alveolar/Bronchiolar Adenoma	1 (5%)			1 (5%)	1 (5%)
Squamous Cell Carcinoma, Metastatic, Skin				1 (5%)	2 (10%)
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
Kidney	(0)	(0)	(0)	(0)	(1)
SYSTEMIC LESIONS					
Multiple Organs	*(20)	*(20)	*(20)	*(20)	*(20)
Leukemia Erythrocytic	1 (5%)			1 (5%)	
Leukemia Granulocytic					1 (5%)
Myelodysplasia					1 (5%)

a - Number of animals examined microscopically at site and number of animals with lesion

* Number of animals with any tissue examined microscopically

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Tumor Summary for Females					
Total Animals with Primary Neoplasms (b)	11	17	18	20	20
Total Primary Neoplasms	15	29	27	42	60
Total Animals with Benign Neoplasms	6	16	17	20	20
Total Benign Neoplasms	7	22	22	31	41
Total Animals with Malignant Neoplasms	2	1	3	9	15
Total Malignant Neoplasms	2	1	3	11	17
Total Animals with Metastatic Neoplasms				5	5
Total Metastatic Neoplasms				8	8
Total Animals with Malignant Neoplasms Uncertain Primary Site					
Total Animals with Neoplasms Uncertain-Benign or Malignant	6	6	2		2
Total Uncertain Neoplasms	6	6	2		2

*** END OF REPORT ***

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors

Control data contained within this report was collected on study 20201-01